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SUTURES INDIA PVT.LTD
SUBMISSION OF PREMARKET NOTIFICATION (510k) FOR ABSORBABLE (POLIGLECAPRONE 25) SUTURE

JUN - 9 2008

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510k SUMMARY as required by: 21CFR 807.92

A. APPLICANT INFORMATION

Name : SUTURES INDIA PVT. LTD

Address : 472 D 13 th Cross, 4 th Phase,
Peenya Industrial Area,
Bangalore–560058. India

PHONE NO. : 91-80-41868000 (30 lines)

FAX NO. : 91-80-41171056

E mail : sales@suturesin.com

Web Address : www.suturesin.com

B. Contact Person : L.G.Chandrasekhar
MANAGING DIRECTOR

C. Date Prepared : 1.4.2008

D. DEVICE NAME

- Trade Name : **MONOGLYDE**
- Common name : Absorbable Surgical Suture,Synthetic (Poliglecaprone 25)
- Classification Name : Absorbable (Poliglecaprone 25) suture

E. PREDICATE DEVICES

A. **Monocryl,** Absorbable (Poliglecaprone 25) sutures, 510(k) Number K930772, Ethicon Incorporation, Somerville, NJ 088760151

B. **Unicaprone** Absorbable (Poliglecaprone 25) Suture, 510(k) Number K072646, United Medical Industries Co.Ltd (UNIMED), Riyadh, SA 11553

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F. DESCRIPTION OF THE DEVICE

MONOGLYDE is synthetic absorbable surgical suture, (Monofilament Poliglecaprone 25). **Monoglyde** is a sterile flexible monofilament thread, composed of Caprolactone. The sutures are inert, non collageneous and non antigenic.

MONOGLYDE is dyed with D&C Violet #2 and it is available undyed also.

G. INTENDED USE OF THE DEVICE

Sutures India's **MONOGLYDE** Absorbable Poliglecaprone suture, is indicated for use in soft tissue approximation, including use in ophthalmic procedures, but not for use in cardio vascular and neurological procedures.

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COMPARISON TABLE SUTURES INDIA'S "MONOGLYDE" ABSORBABLE POLIGLECAPRONE SUTURE TO PREDICATE DEVICES

Comparison Parameters	Monoglyde	Monocryl	Unicaprone
Absorbable (Poliglecaprone 25) suture is a synthetic Absorbable surgical suture. It is a sterile flexible monofilament thread, composed of Poliglecaprone .	Same	Same	Same
The sutures are inert, noncollageneous and nonantigenic.	Same	Same	Same
Absorbable (Poliglycaprone 25) suture is dyed with D&C Violet #2 and being monofilament it is coated	Same	Same	Same
Absorbable (Poliglecaprone 25) suture is indicated for use in soft tissue approximation, including use in ophthalmic procedures, but not for use in cardio vascular and neurological procedures.	Same	Same	Same
Absorbable (Poliglecaprone 25) suture is supplied for single use only.	Same	Same	Same
Absorbable (Poliglecaprone 25) suture is sterilized by E.O. gas method	Same	Same	Same
Absorbable (Poliglecaprone 25) suture is packaged in the same or equivalent manner, and has the same or equivalent labeling claims as that of the predicate devices including indications, warnings, cautions and precautions	Same	Same	Same
Absorbable (Poliglecaprone 25) suture meets the official monograph of the United States Pharmacopeia current edition U.S.P. 29 for extractable color.	Same	Same	Same
Absorbable (Poliglecaprone 25) suture meets the performance requirements defined in the United States Pharmacopeia current edition U.S.P. 29 for Diameter<861>	Same	Same	Same
Absorbable (Poliglecaprone 25)suture meets the performance requirements defined in the current edition of U.S.P. 29 for Tensile strength<881>	Same	Same	Same

Comparison Parameters	Monoglyde	Monocryl	Unicaprone
Absorbable (Poliglecaprone 25) suture meets the performance requirements defined in the ia current edition of U.S.P. 29 for Needle attachment<871>	Same	Same	Same
Absorbable (Poliglecaprone 25) suture meets the performance requirements defined in the United States Pharmacopeia current edition U.S.P. 29 for finished suture Length Requirement (95% of stated label length)	Same	Same	Same
Absorbable (Poliglecaprone 25) suture meets the performance requirements defined in the United States Pharmacopeia current edition U.S.P. 29 for sterility	Same	Same	Same
Absorbable (Poliglecaprone 25) suture is packed in a same or equivalent manner with sterile single or double packing having labeling conforming to 21CFR & U.S.P. 29	Same	Same	Same
Absorbable (Poliglecaprone 25) suture is biologically compatible when tested as per ISO-10993	Same	Same	Same
Absorbable (Poliglecaprone 25) suture is tested and proved to be non toxic, when tested as per ISO-10993 for toxicity	Same	Same	Same

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CONCLUSION

Sutures India's **MONOGLYDE** Absorbable (Poliglecaprone 25) suture is composed of the same material, as that of the predicate devices and has the same design, as do the predicate devices. The suture is manufactured in a manner typical of the industry and equivalent to that used to produce predicate devices. Further the subject device is offered with the same colorant D&C Violet No.2 at a concentration that conforms to the requirements of Title 21 CFR § 74.3602, as are of the predicate devices.

Testing of suture diameter, suture length, knot pull tensile strength, needle attachment strength, extractable color and sterility to methods outlined in USP 29 demonstrates Sutures India's **MONOGLYDE**, Absorbable (Poliglecaprone 25) suture meets or exceeds In-house specifications and are equivalent in terms of the above mentioned predicate devices.

For SUTURES INDIA PVT. LTD.

L. G. CHANDRASEKHAR

L.G.Chandrasekhar
Managing Director

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2008

Sutures India Private Limited
% L.G. Chandrasekhar
472 D 13th Cross, 4th Phase
Peenya Industrial Area
Bangalore-560058
India

Re: K081002
Trade/Device Name: MONOGLYDE
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/L-lactide) surgical suture
Regulatory Class: II
Product Code: GAM
Dated: May 22, 2008
Received: May 27, 2008

Dear L.G. Chandrasekhar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number : K081002

Device Name: **MONOGLYDE**
ABSORBABLE SURGICAL SUTURE (SYNTHETIC)
(MONOFILAMENT POLIGLECAPRONE 25)

Indications For Use:

MONOGLYDE IS A SYNTHETIC ABSORBABLE (POLIGLECAPRONE 25) SURGICAL SUTURE, STERILE FLEXIBLE STRAND, PREPARED AND SYNTHESIZED FROM THE MONOMERS, POLYGLYCOLIC ACID 75% AND CAPROLACTONE 25% AND IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, BUT NOT FOR USE IN OPHTHALMIC SURGERY, CARDIO-VASCULAR AND NEUROLOGICAL TISSUES

Neil R. P. Ogden for mam

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081002

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)